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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,023	03/30/2004	Larry E. Overman	UCIVN-033C	1012

33197 7590 09/22/2006

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,023	OVERMAN ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20040330*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-46 are pending in this application.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating specific tumors for which test data is provided in Fig. 56-62, does not reasonably provide enablement for the treatment of all tumors and viral infections in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The instant claims 41-43 are drawn to "an antitumor composition"; "an antiviral composition"; and "an antifungal composition" and the specification provides that the recited biological activity is drawn to a therapeutic use, e.g., in treating tumors, viral and fungal infections (see page 23). The instant claims appear to be in 'reach-through' format. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification. Further, there is no disclosure regarding how the patient in need of the recited activity is identified and further, how the therapeutic effect is generally produced in the patient. See MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art.

The specification fails to enable one skilled in the art to use the claimed compounds. The use disclosed in the specification is as therapeutic agents useful to treat a variety of disorders, see page 4, lines 20-21. *In vitro* testing procedures and assays are disclosed on pages 127-129, and the anti-tumor activity for some of the compounds of the invention against a select group of tumors is provided in Fig. 56-62, however, there is nothing in the disclosure regarding how this *in vitro* data correlates to the treatment of the all tumors encompassed by the instant claims. The examples disclosed in the specification are structurally very different from the other compounds having different carboxylic acid protecting groups or ω-alkoxycarboxylic acid/ester groups, such that there is no reasonable extrapolation could be made by one skilled in the art regarding the activity of the instantly claimed compounds. Furthermore, this area of receptor interactions are in general highly structure specific and unpredictable. There is no reasonable basis for assuming that the myriad of compounds embraced by the instant claims will all share the same

physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art (directed to integrin receptor modulators) for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also, see MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

There are no known compounds of similar structure, which have been demonstrated to treat all of the diseases due to fungal infections. Some of the state of the art reference statements are provided below to show the unpredictability of the art: Lipman (BMJ 1997): "With so many variables, the diagnosis of candida infection in practice remains a clinical decision based on inference. Disseminated fungal infection may be diagnosed with certainty if a patient develops endophthalmitis or a positive fungal culture is made from an organ such as the kidney or lung. However, the number of positive blood cultures or number of colonised sites required for such a diagnosis remains uncertain."

Claim 45 specifically recites 'treating viral infections', however, there is no common mechanism by which all viral infections arise. There are more than 400 distinct viruses that infect humans producing a wide range of diseases. Cecil Textbook of Medicine states - "for

many viral infections, no specific therapy exists. Proper use of antivirals requires specific viral diagnosis" (see the enclosed article, page 1742).

Claim 44 is drawn to 'a method for treating tumors'. No compound has ever been found to treat tumors of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of oncology. Cecil Textbook of Medicine states - "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the enclosed article, page 1004). Different types of cancers affect different organs and have different methods of growth and harm to the body. Also see *In re Buting*, 163 USPQ 689 (CCPA 1969), wherein 'evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers'.

(Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements).

There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the compounds commensurate in scope with claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the compounds as therapeutic agents.

Note: The instant composition claims 41-43 are recite a particular 'intended use' in the preamble. See MPEP § 2164.01(c). When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. In contrast, when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-10, 22-32 and 38-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Coffey et al. (J. Am. Chem. Soc., 2000, 122, 4904-4914). The instant claims read on reference disclosed compounds and the synthetic procedures thereof, see the compounds disclosed in page 4904, 4908, 4909 and the Schemes in page 4910.

2. Claims 1-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Coffey et al. (J. Am. Chem. Soc., 2000, 122, 4893-4903). The instant claims read on reference disclosed compounds and the synthetic procedures thereof, see the compounds and the synthetic schemes disclosed in pages 4893-4903. The reference further teaches that the compounds exhibit a variety of pharmaceutical activities including antiviral, antifungal, and against tumors, see page 4894.

Note: Applicant's claim for domestic priority under 35 U.S.C. 119(e) based on application No. 60/142,027 and 60/142,028 filed June 30, 1999 is acknowledged. However, the provisional applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the claims of this application. Particularly, the provisional applications do not fully support the instant R definition in the claims.

3. Claims 1-10, 22-32, 42 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Mai et al., WO 93/01193. The instant claims read on reference disclosed compounds, see the compound VI (page 23) and VIa (page 27).

4. Claims 1-10, 22-32 and 38-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al., WO 98/46575. The instant claims read on reference disclosed compounds and the corresponding synthetic procedures, see the compounds disclosed in pages 2-3.

5. Claims 1-19 and 41-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Snider et al. (J. Am. Soc. 1994). The instant claims read on reference disclosed compounds and corresponding synthesis, see compound 9 in page 550 and the reaction schemes.

6. Claims 1-10, 22-32 and 38-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Rinehart et al., U.S. Patent No. 6,028,077. The instant claims read on the reference disclosed compounds, the corresponding synthesis and the biological activity.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 23-46 and 54-57 of copending Application No. 10/255,994. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims substantially overlap the compounds of the reference claims, see the claims in each of the application. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the

species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have had the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Duplicate Claims

Applicant is advised that should claim 41 be found allowable, claims 42 and 43 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims recite 'an intended use' in the preamble, which does not carry any patentable weight. It is suggested that **a single claim** reciting -- A composition -- be retained in place of the three claims 41-43.

Receipt is acknowledged of the Information Disclosure Statements filed on March 30, 2004 and copies are enclosed herewith.

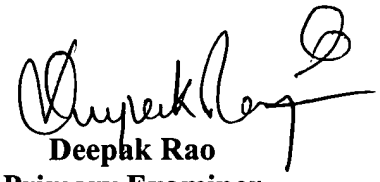
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deepak Rao
Primary Examiner
Art Unit 1624

September 19, 2006